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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,646	09/18/2001	Seth A. Foerster	END-777	8823

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EXAMINER	
QADERI, RUNA S	
ART UNIT	**PAPER NUMBER**
3737	15

DATE MAILED: 08/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/954,646	Applicant(s) FOERSTER ET AL.
	Examiner Runa S. Qaderi	Art Unit 3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *46-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *46-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10 & 12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

Claim 46 is objected to because of the following informalities: The recitation on line 6 is not a positive method step. A suggestion for a proper method format includes "providing an introduce comprising".

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 46-67 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,228,055. Although the conflicting claims are not identical, they are not patentably distinct from each other because the apparatus of the patent claims is specific to the method of the application claims. Both apparatus and method for marking a particular tissue are specific to each other. Although the patent and application claims belong to a

different statutory class of inventions the tow sets of claims are not distinct to each other.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48, 50, 51, 54, 58-62, and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al.

Regarding claims 48, 50, 51, 60, and 62 the Miller et al. reference teaches a method of marking a particular tissue. A marker element applier 10 is comprised of a tubular introducer needle that is interpreted as having a proximal end and a distal end. A taper distal end 13 satisfies a side exit port as taught by applicant. A marking wire 14 functions as the marker element of the claims. The needle 10 is positioned adjacent the particular tissue, fig. 6 and 7. The plug-drawn force is applied to needle 10 to delivery marking wire 14 to the particular tissue, Fig. 1 and column 4 lines 24-41.

Regarding claims 54, 58, 59, 61, and 65 the Miller et al. reference teaches uses of an x-ray or ultrasound imaging modality to confirm placement and

positioning of marking wire and needle. Under x-ray guidance it is inherent that the wire is radiopaque to provide for visualization.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 46, 47, 49, 52, 53, 55-57 63, 64, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (Pat# 5,221,269)

Regarding claims 46, 47, and 49 the Miller et al. reference teaches a method of marking a particular tissue. A marker element applier 10 is comprised of a tubular introducer needle that is interpreted as having a proximal end and a distal end. A taper distal end 13 satisfies a side exit port as taught by applicant. The structure of a needle further satisfies the limitations to providing proximal opening. A marking wire 14 functions as the marker element of the claims. The needle 10 is positioned adjacent the particular tissue, fig. 6 and 7. The plug-drawn force is applied to needle 10 to delivery marking wire 14 to the particular tissue, Fig. 1 and column 4 lines 24-41. A movable shaft in the needle lumen provides for the plug-drawn force to delivery the marker wire to the particular tissue. The Miller et al. reference does not teach providing the closed distal end, an axial opening at the proximal end, plurality of particular tissue regions to

be marked. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have provided differences in the specific details of the marker delivery device because either structure satisfies the method of marking the particular structure as claimed by the applicant. Further it is well know in the art to mark at a second particular tissue because it is a mere duplication of the same method steps. In addition it is obvious to one of ordinary skill in the art to repeat the method steps such that the desire region or regions are marked.

Regarding claims 52, 53, 55-57, 63, 64, and 65 the Miller et al. references does not recite the many available marking agents for marking tissue. The method of delivery the marking element to the particular tissue as taught by Miller et al. is capable of delivery of liquids, it is well know to use a needle to deliver liquid. The use of a wire marking element makes the method of Miller et al. capable for use of other solids as well. Finally it would have been obvious to provide for the claimed marking agents as the marker of Miller et al. because any available marking agent can be used to satisfy the method as disclosed by the applicant.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Markam (4,774,948) teaches marking and retracting needle having retrievable stylet.

2. O'Neill (4,986,279) teaches localization needle assembly with reinforced needle assembly.
3. Marcadis et al. (5,158,565) teaches localization needle assembly.
4. Spencer et al. (5,127,916) teaches localization needle assembly.
5. Rank et al. (5,234,426) teaches helical-tipped lesion localization needle device and method of using the same.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 308-8155. The examiner can normally be reached on Mon-Fri 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis W. Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

RSQ

DENNIS RUHL
PRIMARY EXAMINER